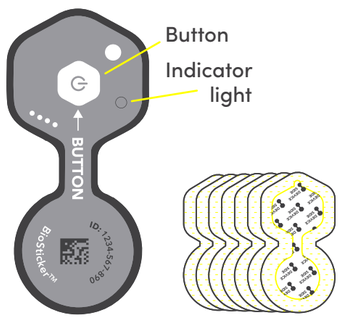
BioSticker™

Instructions for Use

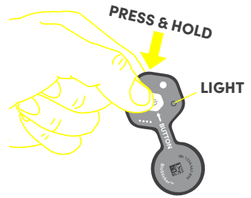
For complete instructions, visit:
BioIntelliSense.com/support

DEVICE + COMPONENTS OVERVIEW

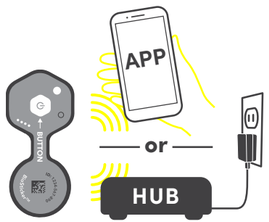


GET STARTED

1 **PRESS AND HOLD** the button for **4 SECONDS**. The light will blink **YELLOW** (indicating that the device is ready to be activated).



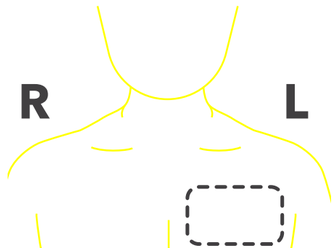
2 **ACTIVATE** your BioSticker with the designated **APP** or **HUB DEVICE** indicated in your program's instructions.



3 **CONFIRM BIOSTICKER ACTIVATION** by pressing the button and verifying that the light blinks **GREEN, 4 TIMES.**

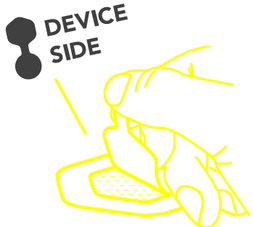
If the blink pattern is different or the light does not blink, refer to the **Button Light Pattern guide** after step 10 for guidance.

4 Locate placement area on **UPPER LEFT CHEST**, two inches below collar bone.

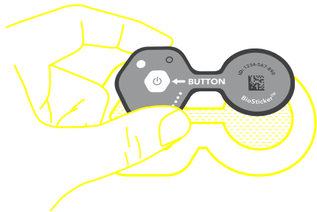


5 **TRIM ANY BODY HAIR** using only an electric trimmer and **CLEANSE AREA** with a warm, damp cloth.

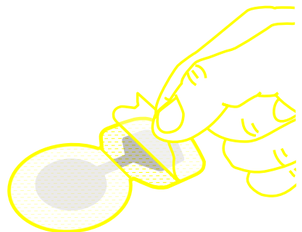
6 **TAKE** one adhesive. Peel the backing from **DEVICE SIDE** of the adhesive.



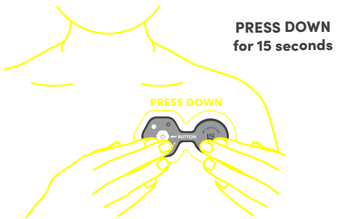
7 Place the **BIOSTICKER** on the exposed adhesive.



8 Turn the device over and remove remaining adhesive backing.



9 **ADHERE** BioSticker to the upper left chest, horizontally or vertically. Apply pressure for **15 SECONDS.**

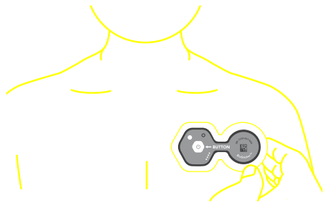


10 Press the button to check the device status. Refer to the **Button Light Pattern guide** below.

PATTERN	MEANING
10 yellow blinks	Not activated
4 green blinks	Actively monitoring
Alternating green + yellow blinks	Monitoring complete
Solid red light or no light	Device error — contact support

REPLACE YOUR ADHESIVE

- When no longer sticky.
- If you experience minor irritation or redness in placement area.



REMOVE adhesive from bottom of device. Follow steps 4 - 9 to put on a new adhesive and reapply the device.

When replacing the adhesive, it is advised to apply the device in a different location within the placement area.

INTENDED USE

The BioSticker™ is a remote monitoring wearable device intended to collect physiological data in home and healthcare settings.

The data can include heart rate, respiratory rate, skin temperature, and other symptomatic or biometric data.

The device is intended for use on users who are 18 years of age or older.

The device does not output heart rate or respiratory rate measurements during periods of motion or activity.

The device is not intended for use on critical care patients.

NOTICE: Use of the BioIntelliSense Product(s) is subject to our Website and Product User Terms of Use (BioIntelliSense.com/legal/website-and-product-user-terms-of-use) and our Website and Product Privacy Policy (BioIntelliSense.com/ legal/privacy-policy) By using the Product(s), you indicate you have read these terms and policies and that you agree to them, including the limitations and disclaimers of liability. In particular, you understand and consent that use of the Product(s) measures and records personal information about you, including vital sign and other physiologic measurements. That information may include respiratory rate, heart rate, temperature, activity level, sleep duration, body position, step count, gait analysis, coughing, and other symptomatic or biometric data. You understand that the Product(s) do not render medical advice or diagnose or prevent any specific disease, including any communicable disease or virus. If you have any concerns about your health, including whether you have been exposed to or have contracted any disease or virus, immediately contact your healthcare provider.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

TROUBLESHOOTING & FAQS

How do I know my device is working? Press and release the device's button. The device light will blink **GREEN 4 TIMES**. If your device light is blinking a different color, please reference the Button Press Light Patterns table on the front page.

Can I shower or exercise with the device? Yes, the device is water resistant and can be worn during showers and exercise. Do not apply any oil or lotion to the placement area as it will reduce adhesion of the device to the skin.

Can I swim or bathe with my device? No, although the device is water resistant it should not be submerged underwater including while swimming or bathing. Prolonged submersion underwater may cause damage to the device and may cause the device to loosen from the skin. If removed for swimming or bathing, replace the adhesive and reapply the device to the placement area.

I'm experiencing some skin irritation, what should I do? Minor skin irritation and itching may occur while wearing the device. If a severe reaction develops (i.e. hives or blisters), discontinue wearing and contact your physician.

How long should I wear my device? Please wear your device for the entire monitoring period. Each adhesive is designed for longer wear duration, typically up to 7 days, before replacing. For additional adhesive tips, visit BioIntelliSense.com/support.

How do I know if my monitoring period is complete? At the end of the monitoring period, after pressing the button, the light will alternate between green and yellow.

I've tried powering on the device several times, and the light still won't blink yellow. What do I do? Contact Customer Support immediately. You may be instructed to return the device and may receive a replacement kit if more data is needed for the monitoring period.

WARNINGS & PRECAUTIONS

- **DO NOT** wear device over excessive body hair. Excessive body hair should be trimmed using only an electric trimmer, before application.
- **DO NOT** place on broken skin including wounds, sores, or abrasions.
- **DO NOT** submerge the device underwater. Submerging the device for an extended period of time may damage the device.
- **DO NOT** continue wearing if severe discomfort or irritation occurs.
- **DO NOT** exert excessive force, drop, modify, or attempt to take apart the device. Doing so may cause malfunction or permanent damage.
- **DO NOT** wear or use the BioSticker device during a magnetic resonance imaging (MRI) procedure or in a location where it will be exposed to strong electromagnetic forces.
- Keep the BioSticker device away from children and pets. The device is a choking hazard and is harmful if swallowed.
- **REMOVE** the BioSticker device prior to any defibrillation events. Clinical validation has not been performed for persons who have a defibrillator, pacemaker device, and other implantable devices.
- Press the device's button regularly to check the indicator light and to verify that the device is in active monitoring mode.
- Heart Rate and Respiratory Rate data is only reported when the wearer is at rest.

Manufactured by BioIntelliSense, Inc.
570 El Camino Real #200, Redwood City, CA 94063

SUPPORT

In the event of a medical emergency, contact your medical emergency service.

For additional support including tips on long-term wear and adhesive information:
Email: **support@biointellisense.com**
Call: **888.908.8804 (US ONLY)**

Use QR code or visit:

BioIntelliSense.com/support

OCTOBER 2021 BSI-LBL-DWG-IFU Rev.8